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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/522,169 | 11/16/2005 | Reinhard Nubbemeyer | SCH-1947-02 | 3554 |

23599 7590 08/13/2009

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| EXAMINER | |
|---|---|
| CHUI, MEI PING | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1616 | |

| NOTIFICATION DATE | DELIVERY MODE |
|---|---|
| 08/13/2009 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

| **Advisory Action Before the Filing of an Appeal Brief** | **Application No.** 10/522,169 | **Applicant(s)** NUBBEMEYER ET AL. | |
|---|---|---|---|
| | **Examiner** MEI-PING CHUI | **Art Unit** 1616 | |

***--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***

THE REPLY FILED 30 July 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): 35 U.S.C. 112 second paragraph for claims 5-12.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-12*.
   Claim(s) withdrawn from consideration: *13-16*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see continuation below.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Mina Haghighatian/
Primary Examiner, Art Unit 1616

Continuation of Box 11:

The request for reconsideration filed on 07/30/2009 has been fully considered but does NOT place the application in condition for allowance:

(1) Applicants argue that neither the office action nor the prior art of record teach or suggest why one of ordinary skill in the art would have selected the two cited components and use in the claimed invention, especially when nowhere in the prior art, namely Krattenmacher et al., dislcoes that a joint administration with an androgen is useful for male contraception (Remarks: page 6).

The arguments are not persuasive because the prior art in combination teach and suggest all the claimed subject matters and claimed limitations (see Office Action, dated on 04/30/2009).

As stated in the previous Office Action, the primary prior art, namely Bohlmann et al., teaches the use of an androgenic 11β-halogen steroid for the utility of male menopause or male birth control therapy. Importantly, Bohlmann et al. also specifically discloses the claimed 11β-halogen steroid: 11β-fluoro-17β-hydroxy-7α-methyl-estr-4-en-3-one and suggest that it can be used in combination with a progestogen compound for controlling male fertility (see Office Action, dated on 04/30/2009, page 4 and 5).

The secondary prior art, namely Krattenmacher et al., teaches that compounds of 14,17-C2-bridged steroids of formula (I) are gestagens, which have good gestagen action and are suitable for use in contraceptive purposes (or referred as progestogenic action). Krattenmacher et al. even specifically teach the instant gestagen (21S)-21-hydroxy-21-methyl-14,17-ethano-19-norpregna-4,9,15-triene-3,20-dione as one of the preferred gestagen of formula (I) (see Office Action, dated on 04/30/2009, page 6 and structure of compound B).

Thus, one of ordinary skill in the art would have been motivated to utilize the 11β-halogen steroid: 11β-fluoro-17β-hydroxy-7α-methyl-estr-4-en-3-one (which is known to have the utility in male birth control) and also incorporates the gestagen (21S)-21-hydroxy-21-methyl-14,17-ethano-19-norpregna-4,9,15-triene-3,20-dione (which is known to be suitable for use in contraceptive purpose) to arrive at the instant composition for controlling male fertility, as suggested by Bohlmann et al. and Krattenmacher et al.

(2) With respect to the arguments of the prior art Krattenmacher et al. does not teach the claimed gestagen of formula (I) is useful for male contraception and the claimed male contraceptive combination produces synergistic effect (Remarks: page 6-7), it is noted that the features upon which Applicants rely are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claim(s). See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

(3) In summary, the scope of the instant claims are not altered and thus, it is the examiner's position that the prior rejections of record (mailed on 04/30/2009) remains valid and will be maintained for the reason of record.